UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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| PFIZER INC., PHARMACIA CORP., PHARMACIA & UPJOHN INC., PHARMACIA& UPJOHN COMPANY, G.D. SEARLE & CO, G.D. SEARLE LLC, SEARLE LLC (DELAWARE) and SEARLE LLC (NEVADA)<br><br>Plaintiffs,<br>v.<br><br>TEVA PHARMACEUTICALS USA, INC.<br><br>Defendant. | CIV. ACTION NO. 04-754 (JCL)<br><br>**OPINION**<br><br>Pfizer's Motion In Limine No. 2 |

**LIFLAND, District Judge**

This case arises out of Teva Pharmaceuticals U.S.A., Inc.'s ("Teva" or "Defendant") alleged infringement of U.S. Patent Nos. 5,466,823; 5,563,165; and 5,760,068 (the "patents-in-suit"), which are held by Pfizer, Inc., Pharmacia Corp., Pharmacia & Upjohn Inc., Pharmacia & Upjohn Company, G.D. Searle & Co., G.D. Searle LLC, Searle LLC (Delaware), and Searle LLC (Nevada) (collectively "Pfizer" or "Plaintiffs"). The patents-in-suit are directed toward celecoxib, the active ingredient in Celebrex, and a broad genus of compounds that includes celecoxib, pharmaceutical compositions including such compounds, and methods

of using such compounds.

Before the Court is Pfizer's motion in limine No. 2 to preclude the testimony of several of Teva's expert witnesses. Pfizer seeks to preclude Teva from proffering testimony from the following experts: Dr. Keith Leffler (economist); Dr. Simon Helfgott (rheumatologist); Mr. William Schultz (attorney); and Dr. Michael Wolfe (gastroenterologist).

Under Federal Rule of Evidence 702, a court may allow an expert to give testimony that would otherwise be inadmissible

> [i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, [and] if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

F.R.E. 702. The Third Circuit has "explained that Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003).

> Qualification refers to the requirement that the witness possess specialized expertise. . . . Secondly, the testimony must be reliable; it "must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his on her belief. . . . Finally, Rule 702 requires that the expert testimony must fit the issues in the case. In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact.

Id. (internal citations omitted). Pfizer contends, *inter alia*, that the testimony of each of the expert witnesses listed above should be precluded because it fails to meet one or more of the trilogy of requirements.[1]

A. Dr. Leffler

Pfizer intends to rely on Celebrex's commercial success as a secondary consideration suggesting non-obviousness. It is well-established that the commercial success of an invention may be strong evidence of non-obviousness. See, e.g., Demaco Corp. v. F. Von Langsdorff Licensing, Ltd., 851 F.2d 1387, 1391 (Fed. Cir. 1988). However, evidence showing sale of a large number of goods supposedly embodying the claimed invention does not necessarily demonstrate non-obviousness: "The success must be due to the claimed features of the invention, rather than factors such as advertising, superior workmanship, or other features within the commercialized technology." Roger Schechter and John Thomas, Principles of Patent Law 164. Dr. Leffler plans to testify that Celebrex's commercial success is due to Pfizer's marketing efforts, not to claimed features of

[1] Motions to exclude evidence are committed to the Court's discretion. See In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 749 (3d Cir. 1994) (explaining that on a motion to preclude proffered expert testimony, the trial court's inquiry is a flexible one, and its decision to admit or exclude expert testimony is reviewed under an "abuse of discretion" standard) (internal citations omitted).

the invention. Pfizer contends that this testimony should be precluded because it fails to satisfy the second requirement of Rule 702—reliability. Specifically, Pfizer argues that Dr. Leffler's opinions are not based on any established methodology, but rather on an untested assumption that Celebrex's properties are not superior to other non-steroidal anti-inflammatory drugs ("NSAIDs"). The Court disagrees.

An expert "must consider enough factors to make his or her opinion sufficiently reliable in the eyes of the court . . . [but the] expert need not consider every possible factor to render a 'reliable' opinion." MicroStrategy Inc. v. Business Objects, S.A., 429 F.3d 1344, 1355-1356 (Fed. Cir. 2005). Moreover, a district court is not required to preclude expert testimony simply because the proposed expert could have performed his or her analysis in a better manner. See Kannankeril v. Terminix Int'l, 128 F.3d 802, 809 (3d Cir. 1997). As the Third Circuit has stated:

> A judge should find an expert opinion reliable under Rule 702 if it is based on "good grounds," i.e., if it is based on the methods and procedures of science. . . . The grounds for the expert's opinion merely have to be good, they do not have to be perfect. The judge might think that there are good grounds for an expert's conclusion even if the judge thinks . . . that a scientist's methodology has some flaws such that if they had been corrected, the scientist would have reached a different result.

In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 745 (3d Cir. 1994). The Court finds that this standard is met here. Dr. Leffler considered, *inter alia*, sales and marketing data including data related to prescriptions for Celebrex and other NSAIDs, Celebrex's promotional expenditures, expert medical opinions, and academic literature on drug promotion and sales. (See Declaration of Daniel Reisner in Support of Pfizer's Motion in Limine No. 2 (hereinafter, "Reisner Decl."), Ex. A.) He applied established economic principles to this data, and explained how it informed his ultimate conclusions. (Id.)

Pfizer's contention that Dr. Leffler's testimony is unreliable because he failed to conduct his own independent analysis of the comparative therapeutic properties of Celebrex and other NSAIDs is unavailing. Initially, as an economist, it would have been inappropriate for Dr. Leffler to personally conduct a medical study or reach independent conclusions as to Celebrex's therapeutic advantages. Moreover, Dr. Leffler plans to testify regarding a plethora of factors other than therapeutic benefits that he believes account for Celebrex's commercial success. Even if Dr. Leffler is inaccurate—and there in fact are therapeutic advantages to Celebrex over other NSAIDs—this would not obviate his ultimate conclusion that factors such as marketing and promotion, not these therapeutic benefits, were ultimately responsible for Celebrex's commercial success.

Finally, the Court notes that Pfizer's concerns regarding Dr. Leffler's methods "go[] more to the weight of the evidence than to its admissibility." Liquid Dynamics Corp. v. Vaughan Co., 449 F.3d 1209, 1221 (Fed. Cir. 2006). As such, these concerns are appropriately addressed in cross examination rather than in a motion in limine to preclude the evidence altogether. See In re TMI Litig., 193 F.3d 613, 692 (3d Cir. 1999) ("'So long as the expert's testimony rests upon "good grounds," it should be tested by the adversary process–competing expert testimony and active cross-examination– rather than excluded from jurors[']' scrutiny . . . .'") (quoting Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co., 161 F.3d 77, 85 (1st Cir. 1998)); see also Daubert v. Merrell Dow Pharms., 509 U.S. 579, 596 (1993) ("[V]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

Accordingly, Pfizer's motion to preclude Dr. Leffler's testimony will be denied.

B. Dr. Helfgott

Dr. Helfgott is a practicing rheumatologist at Brigham and Women's Hospital (BWH) in Boston Massachusetts, an Associate Professor of Medicine at Harvard Medical School, and Director of Education and Fellowship Training at

the Division of Rheumatology at BWH. Teva plans to offer Dr. Helfgott's testimony concerning Celebrex's therapeutic properties, the absence of therapeutic advantages over other NSAIDs, and physician prescribing practices—specifically the role of marketing materials in influencing physicians to prescribe Celebrex. Pfizer objects to this evidence on two grounds.

Pfizer argues that Dr. Helfgott's testimony should be precluded because he relied only on documents that were hand-selected and provided to him by Teva's counsel. The Court disagrees. As Dr. Helfgott explained during his deposition, he "initiated the request to see what [internal marketing] materials would be available." He was subsequently "provided with lots of documents that [he] could look at," and was "involved in the selection of the documents that ended up being referenced in his reports." (Declaration of Michael Patunas in Opposition to Pfizer's Motion in Limine No. 2, Ex. M, at 23-24, 26.)

Pfizer also argues that Dr. Helfgott's testimony should be excluded in its entirety because it is speculative and not based on a reliable methodology. The Court finds that some aspects of the proposed testimony are indeed speculative and thus inadmissible. However, the Court will not preclude Dr. Helfgott's testimony in its entirety because other aspects of his testimony are appropriately grounded in his experience, training, and specialized knowledge.

The first subject addressed in Dr. Helfgott's expert report is the history and development of Celebrex and NSAIDs in general. As an expert in the field of rheumatology, Dr. Helfgott is "fully qualified to opine on the medical facts and science" regarding Celebrex and NSAIDs. In re Diet Drugs Prods. Liab. Litig., No. 1203, 2000 U.S. Dist. LEXIS 9037, at *37 (E.D. Pa. June 20, 2000). His opinions on this topic are based on many years of training and experience in the field, as well as reference to several academic medical journals. Accordingly, the Court finds Dr. Helfgott's testimony as to this subject to be appropriate and admissible.

The next subject addressed in Dr. Helfgott's report is the factors that affected physicians' choice among available NSAIDs before Celebrex entered the market. Dr. Helfgott's expertise in rheumatology "do[es] not qualify [him] as [an] expert[] about what all doctors generally consider when making prescription decisions." Diet Drugs Liab. Litig., 200o U.S. Dist. LEXIS 9037, at *36. Nor does it qualify him to testify as to all physicians' understandings of the risks and benefits of NSAIDs. See In re Rezulin Prods. Liab. Litig., 309 F.Supp.2d 531, 555-56 (S.D.N.Y. 2004).

Teva argues that Dr. Helfgott should be permitted to testify on these subjects because his opinions "are based on his 20 years practicing rheumatology

and prescribing NSAID therapies for the treatment of chronic pain." (Teva's Memorandum in Opposition to Pfizer's Motion in Limine No. 2, at 9.) This is not a sufficiently reliable basis for his broad opinions on the prescribing practices and general understanding of all physicians. A similar argument was made, and rejected, in Advanced Medical Optics, Inc. v. Alcon, Inc., No. 03-1095 (KAJ), 2005 U.S. Dist. LEXIS 5803 (D. Del. Apr. 7, 2005). There, an opthamologist planned to testify regarding the competitive advantages accruing to pharmacoemulsification machines that incorporated the claimed invention, Occlusion Mode.[2] As is the case here, the doctor was clearly qualified in his field of medicine, but had no specialized expertise regarding sales or market analysis, and had conducted no scientific studies or surveys concerning purchasing practices of other doctors in his field. The proponent of the testimony argued that the opthamologist should be permitted to testify because he was an "expert consumer" of pharmacoemulsification products, who was familiar with various pharmacoemulsification machines, had been performing cataract surgery for thirty years, and was responsible for approving all purchases for his department at a large eye care center.

The Court held that being an "expert consumer" did not remedy the doctor's

[2] Pharmacoemulsification machines are used in cataract surgery.

lack of expertise in sales and market trends, and did not overcome the lack of a scientific basis for his opinions. Id. at *9. The Court precluded the opthamologist from testifying regarding the competitive advantages of Occlusion Mode or the general preferences of other surgeons in his field. Id. at *9-*13.

Here, as in Advanced Medical Optics, Dr. Helfgott's testimony regarding what physicians in general think/know and how they make prescription decisions is speculative and not based on reliable evidence.[3] Accordingly, this testimony will be precluded. The court notes, however, that this section of Dr. Helfgott's report also contains opinions concerning the general factors that physicians may consider when selecting an NSAID to prescribe to a patient. As an expert in the field of rheumatology, Dr. Helfgott, is qualified to opine on these factors and may properly explain these considerations to the Court.

The next section of Dr. Helfgott's report is entitled, "Celebrex is Marketed as the First COX-2 Compound." The first three paragraphs of this section (paragraphs 35-37) contain general information on the history and development of NSAIDs and Celebrex. As explained above, such testimony is appropriate and

[3] One striking example of an assertion in this section that self-evidently purports to explain how physicians make prescription decisions is Dr. Helfgott's statement that "a physician's choice among NSAIDs is largely driven by habit and convenience." In the absence of a reliable basis, such an opinion is not admissible. (Reisner Decl., Ex. C, at ¶ 27.)

admissible. In the remainder of this section (paragraphs 38-40), Dr. Helfgott asserts that the marketing claims about Celebrex "fueled physician and patients expectations," but that these claims were later shown to be unsubstantiated. As an expert in rheumatology, Dr. Helfgott may render an opinion on the accuracy of Celebrex's marketing materials. He is "fully qualified to opine on the medical facts and science of [Celebrex] and to compare that knowledge with what was provided in the text of [the marketing materials]." Diet Drugs Liab. Litig., 2000 U.S. Dist. LEXIS 9037, at *37. However, he may not opine as to physicians' or patients' understanding of these materials or the effect that these materials had on their prescription choices. Dr. Helfgott's opinions on this subject are speculative and not based on a reliable methodology.

In the next section of his report Dr. Helfgott asserts that Celebrex prescriptions were heavily influenced by advertising and promotion. This opinion is based primarily on his personal experiences with Celebrex's marketing representatives and patients who requested Celebrex prescriptions, as well as "common sense," (Reisner Decl., Ex. F, at 424-25), and informal discussions with other doctors. This is not a sufficiently reliable basis for his opinions.

This is not to say that "the personal experience or knowledge of the expert alone is not to be trusted. To the contrary, the text of Rule 702 expressly

contemplates that an expert may be qualified on the basis of experience." United States v. Frazier, 387 F.3d 1244, 1296 (11th Cir. 2004); see also Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 150 (1999); Maiz v. Virani, 253 F.3d 641, 668-69 (11th Cir. 2001) ("[T]here is no question that an expert may still properly base his testimony on 'professional study or personal experience.'"). However, the Court is not persuaded that personal knowledge and experience Dr. Helfgott relies upon in support of his opinion forms a sufficient basis for his broad conclusions concerning the impact of sales and marketing efforts on Celebrex prescriptions. The fact that he received frequent visits from Pfizer representatives, and that several of his patients requested Celebrex prescriptions does not alone support a conclusion that Celebrex's prescriptions were heavily influenced by advertising and promotion.

In the final section of Dr. Helfgott's report, he asserts that the claimed superiority that drove Celebrex prescriptions was misleading and falsified. For the reasons discussed above, this testimony is permissible since Dr. Helfgott is "fully qualified to opine on the medical facts and science of [Celebrex] and to compare that knowledge with what was provided in the text of [the marketing materials]."

Diet Drugs Liab. Litig., 2000 U.S. Dist. LEXIS 9037, at *37.[4]

In summary, Dr. Helfgott's may testify concerning the history and development of Celebrex and NSAIDs in general, the general factors that physicians may consider when making prescription decisions, and the accuracy of Celebrex's marketing and promotional materials. He may not testify concerning what all doctors generally consider when making prescription decisions, what all physicians believe or know about the risks and benefits of NSAIDs, or the extent to which marketing drove Celebrex's prescriptions.[5]

C. Mr. Schultz

Mr. Schultz is an expert in FDA regulation. Teva plans to offer his testimony regarding FDA regulation of the labeling, advertising, and promotion of prescription drugs, and to what extent Pfizer's actions with respect to Celebrex have complied with the FDA's statutory and regulatory requirements. The Court assumes, for present purposes, that this testimony is relevant to Teva's position on

[4] This section also includes a few paragraphs concerning the cardiovascular effects of Celebrex. Dr. Helfgott's proposed testimony on cardiovascular issues will be addressed below in Section D.

[5] Pfizer also argues that Dr. Helfgott should be precluded from offering opinions about the state of mind of Pfizer and its employees and about FDA regulations. The Court does not see any such opinions in Dr. Helfgott's proposed testimony.

the secondary consideration of commercial success. Pfizer argues that Mr. Schultz's testimony should be precluded because it is merely a recitation of selected language from FDA regulatory documents. The Court disagrees.

Mr. Schultz's expert report provides general information regarding the FDA's regulation of prescription drug labeling, as well as an overview of the FDA's regulation of Celebrex and Pfizer's promotion of Celebrex. Mr. Schultz ultimately concludes that Pfizer violated applicable FDA regulations governing advertising of approved drug products in several ways. Given these conclusions, the Court cannot agree with Pfizer's assertion that Mr. Schultz does not offer any opinions and merely recites the text of FDA documents. The report does refer to, and sometimes quotes from, FDA documents; however, such citations are proper—and indeed necessary—in order to set forth the basis for Mr. Schultz's ultimate conclusions.

Pfizer also argues that Mr. Schultz's testimony should be precluded because he only reviewed material hand-selected by Teva's counsel, and ignored information contrary to his opinion. Teva does not respond to this argument. Nevertheless, the Court is not persuaded that Mr. Schultz's testimony should be precluded on this ground.

Pfizer states that "Mr. Schultz's testimony is based primarily on selected

FDA regulatory letters sent to Pfizer," but does not cite any source for this conclusory statement. (Pfizer's Memorandum in Support of its Motion in Limine No. 2, at 21.) Pfizer points to no deposition testimony or other evidence indicating that Mr. Schultz failed to conduct an independent analysis and instead relied exclusively on documents selectively furnished by Teva's counsel. Pfizer does point to evidence that Mr. Schultz failed to consider some documents that might have affected his opinions; however, the Court finds this is an issue best addressed by cross-examination. Mr. Scultz's failure to consider all relevant documents may impact the validity of his opinions or the weight they should be accorded, but the Court does not find that it renders his entire testimony inadmissible.

D. Cardiovascular Testimony of Drs. Helfgott and Wolfe

This Court previously granted Teva's motion to preclude Dr. Zusman's testimony on the alleged superior cardiovascular safety profile and cardiovascular properties. (See Pfizer v. Teva, No. 04-754, Opinion and Order on Teva's Omnibus in Limine Motion No. 6.) Teva agreed not to offer the testimony of Drs. Wolfe and Helfgott with respect to cardiovascular issues if its motion to limit Dr. Zusman's testimony was granted. (Teva's Opposition to Pfizer's Motion in Limine No. 2, at 18 ("If the Court grants Teva's motion to exclude the opinion testimony of Dr. Zusman, Teva will honor its original proposal not to offer the

testimony of Drs. Wolfe and Helfgott with respect to cardiovascular issues.").) Accordingly, Pfizer's motion to preclude Drs. Wolfe and Helfgott's testimony on cardiovascular issues will be denied as moot.

E. Conclusion

In summary, Pfizer's motion to preclude the testimony of several of Teva's expert witnesses will be granted with respect to aspects of Dr. Helfgott's testimony, denied as moot with respect to Drs. Wolfe and Helfgott's testimony on cardiovascular issues, and denied in all other respects.

/s/ John C. Lifland, U.S.D.J.

Dated: November 9, 2006